

# FSIS Guideline for Industry Response to Customer Complaints

2019

This guideline is designed to help meat and poultry establishments develop a written program to respond to customer complaints. This guidance covers:

- How to respond to customer complaints of adulterated or misbranded meat and poultry products
- The notification requirements in 9 CFR 418.2

## **Preface:**

FSIS developed this guideline to communicate best practices to the meat and poultry industry for responding to customer complaints. The guideline was developed with appropriate review and public participation. This guideline follows the procedures in the Office of Management and Budget's (OMB) "Final Bulletin for Agency Good Guidance Practices" (GGP). You can find more information on the Food Safety and Inspection Service (FSIS) [Web page](#). The guideline was developed with appropriate review and public participation. The red meat and poultry trade associations, along with their members, have developed a related document, [Industry Best Practices for Customer Complaints of Foreign Material in Meat and Poultry Products](#). Establishment personnel may want to use guidance from both documents when developing a response to customer complaints.

## **What is the purpose of this guideline?**

The purpose of this guideline is to provide industry with reference material on best practices for responding to customer complaints of adulterated and misbranded meat and poultry products. FSIS developed this document in response to an increase in the number of recalls of meat and poultry products adulterated with foreign materials. In many cases, the recalling establishments had received multiple customer complaints prior to these recalls. FSIS specifically developed this document to address foreign material customer complaints, but establishments can apply the information to other customer complaints of adulterated or misbranded products in commerce. This guideline represents FSIS's current thinking on this topic and should be considered usable as of the issuance date.

## **Who is this guideline designed for?**

FSIS is issuing this document to assist all FSIS-regulated establishments that slaughter or further process inspected meat and poultry products to develop and implement procedures for responding to customer complaints to prevent recurrence of similar product adulteration or misbranding events. This document is not regulatory. Establishments may choose to adopt different procedures than those outlined in this guideline.

## **How can I comment on this guideline?**

FSIS is seeking comments on this guideline as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days and the document will be updated in response to the comments.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal Online submission at [regulations.gov](http://www.regulations.gov): This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments.

Mail, including - CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250-3700.

All items submitted by mail or electronic mail must include the Agency's name: FSIS, and document title: FSIS Guideline for Industry Response to Customer Complaints. Comments received will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

### **Is this version of the guideline final?**

No, this version of the guideline, dated February 2019, will be available for public comment until May 15, 2019. After FSIS reviews the comments, it will update this guideline as necessary and respond to public comments.

### **What if I still have questions after I read this guideline?**

If the desired information cannot be found within the guideline, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the [askFSIS](#) database or submit questions through [askFSIS](#). Documenting the questions helps FSIS improve and refine present and future versions of the guideline and associated issuances.

When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter <b>FSIS Guideline for Industry Response to Customer Complaints</b> .
Question Field:	Enter question with as much detail as possible.
Product Field:	Select <b>General Inspection Policy</b> from the drop-down menu.
Category Field:	Select <b>Regulations/Agency Issuances</b> from the drop-down menu.
Policy Arena:	Select <b>Domestic (U.S.) Only</b> from the drop-down menu.

When all fields are complete, press **Continue**.

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## Background:

9 CFR 417.2(a)(1) of the Hazard Analysis and Critical Control Point (HACCP) requirements specifies, *“Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment.”*

9 CFR 416.12(a) of the Sanitation Standard Operating Procedure (Sanitation SOP) regulatory requirements states, *“The Sanitation SOPs shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).”*

9 CFR 416.4(d) of the Sanitation Performance Standards (SPS) states, *“Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.”*

These regulations demonstrate the regulatory requirements that every FSIS-inspected establishment is required to meet to protect product from adulteration and misbranding from all sources, including foreign material contamination. If adulteration occurs, the establishment must implement corrective actions to prevent the adulterated product from entering commerce and, if necessary, to remove product which may have already entered commerce. Depending on how the foreign material contamination or adulteration is addressed in the HACCP system, the establishment will need to determine if HACCP or Sanitation SOP corrective actions are required.

### What is adulterated or misbranded product?

**Adulterated:** A meat or poultry product that is injurious to health or is for any other reason unsafe, unsound, unhealthful, unwholesome, or otherwise unfit for human food.

**Misbranded:** A meat or poultry product that bears a false or misleading label or if any required feature is not prominent.

### What is adulterated or misbranded product?

Meat and poultry products that are contaminated with foreign materials are adulterated under the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA) regardless of the physical characteristics of the foreign material (e.g., shape, size, hardness, etc.).

A meat or poultry product is adulterated, among other circumstances, if it bears or contains any poisonous or deleterious substance that may render it injurious to health; it is unhealthful, unwholesome, or otherwise unfit for human consumption; or it was prepared, packaged, or held under insanitary conditions whereby it may have been rendered injurious to health (see 21 U.S.C. 453(g) and 21 U.S.C. 601(m)).

A meat or poultry product is misbranded if its label is false or misleading, or if it does not contain the required labeling features (see 21 U.S.C. 453(h) and 21 U.S.C. 601(n)).

## **What is the HACCP system?**

The establishment's HACCP system consists of the plans, programs, measures, and procedures that are implemented to prevent, eliminate, or control identified food safety hazards and other adulterants in the products it produces. The HACCP system includes the HACCP plan and Sanitation SOPs, prerequisite programs, and other plans in operation at an establishment to prevent or control food safety hazards and produce product that is safe, wholesome, and properly labeled. Establishments should customize programs for their unique products, operations, and programs.

The establishment's HACCP system should function to prevent any adulterated product from entering commerce, even if the cause of the adulteration is not a food safety hazard (e.g., it does not result in a food to be unsafe for human consumption). For example, an establishment may determine that a specific foreign material does not pose a physical or chemical food safety hazard in the product; however, the presence of the foreign material in a food causes that food to be adulterated and unfit for human consumption. Human food containing a foreign material must be prevented from entering commerce through the proper design and implementation of the establishment's HACCP system.

## **What is Preshipment Review?**

As required in 9 CFR 417.5(c), prior to shipping product (preshipment review), establishments must review the production records of the product, making sure that all processing requirements were met and if necessary all corrective actions were taken. The establishment should not sign preshipment review until it has reviewed all lot specific documentation. Lot specific documentation includes all records associated with that specific production including, but not limited to, critical control point (CCP) monitoring, HACCP verification, corrective actions and also prerequisite programs, testing, and any other applicable programs associated with the production of that lot. Preshipment review indicates that the product has been determined to be free from food safety hazards as well as other causes of adulteration, and is ready for commerce. The review of the appropriate documents and compliance with 9 CFR 417.5(c) occurs before the product leaves the control of the producing establishment and enters commerce.

## How to determine if product has entered commerce?

In general, FSIS considers product to be in commerce when it is no longer under the direct control of the producing establishment. This includes products moving between official establishments and not yet available to institutional or household consumers at the retail level.

FSIS considers the following to be indications that the producing establishment maintains direct control of products, provided the controls are sufficiently documented and HACCP system decisions are consistent with the expressed controls:

- Products are moved between two establishments owned by the same corporation, under a tamper-resistant seal applied by the producing establishment.
- Products are moved under FSIS seal.
- Products are at the establishment or located on premises owned by the producing establishment.

## What are the notification requirements under [9 CFR 418.2](#)?

***§418.2 Notification.*** Each official establishment must promptly notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded meat, meat food, poultry, or poultry product received by or originating from the official establishment has entered commerce, if the official establishment believes or has reason to believe that this has happened. The official establishment must inform the District Office of the type, amount, origin, and destination of the adulterated or misbranded product.

When an establishment has reason to believe that adulterated or misbranded product has entered commerce, the establishment must notify FSIS within 24 hours. The 24-hour period includes weekends or non-work days. Establishments must report within 24 hours, even when they learn that adulterated or misbranded product has entered commerce on a Friday and they do not operate the next day. The regulation applies to both producing and receiving official establishments.

## When is product in commerce?

In commerce: When product is not under the direct control of the producing establishment and is in distribution, this includes movement between FSIS-inspected establishments.

- FSIS considers product to be in commerce when pre-shipment review is signed (unless there are other written methods to demonstrate direct control) and the product is in distribution.
- Individual determinations are made on a case-by-case basis using information including the establishment procedures to demonstrate direct control and the physical location of the product.

If a producing establishment discovers that their products are adulterated or misbranded while the products are still under their direct control, they are not required by [9 CFR 418.2](#) to notify the District Office that the adulterated or misbranded products were produced.

When an establishment is unsure if a finding should be reported to FSIS, it should ask Inspection Program Personnel (IPP) or the District Office for clarification.

### *9 CFR 418.2 vs. FSIS Directive 8140-1*

The regulatory requirement in [9 CFR 418.2](#) to notify the District Office when adulterated or misbranded product has entered commerce applies to establishments, and is separate from the instruction to FSIS inspection personnel found in [FSIS Directive 8140.1](#), *Notice of Receipt of Adulterated or Misbranded Product*. [FSIS Directive 8140.1](#) is an internal notification tool used by FSIS personnel when adulterated or misbranded product has moved between establishments, even if that product has not entered commerce, and the regulatory requirement to notify FSIS described in [9 CFR 418.2](#) does not apply. The establishment is responsible for meeting the regulatory requirement as described in [9 CFR 418.2](#) and for providing information as requested by FSIS personnel to complete FSIS Form 8140-1. However, there is overlap when an establishment has received adulterated or misbranded product that has been in commerce and is required by [9 CFR 418.2](#) to notify the District Office and performs that notification by notifying IPP who then complete FSIS Form 8140-1. The relationship between the regulatory requirements for establishments and the instructions for FSIS personnel is demonstrated in Figure 1. The notification requirements for the receiving and producing establishments are further discussed below.

24 hours starts when the establishment learns or determines that adulterated or misbranded product may have entered commerce

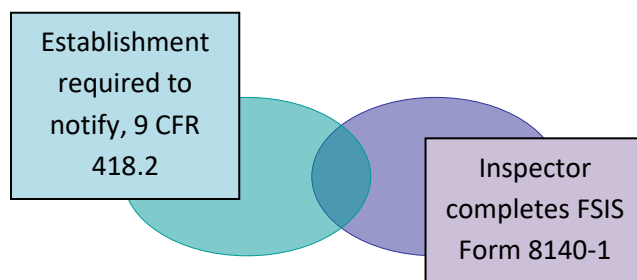


Figure 1: This diagram demonstrates that there is overlap between the regulatory requirements for establishments to notify FSIS outlined in 9 CFR 418.2 and the instructions to FSIS personnel to complete FSIS Form 8140-1, but that they are two separate policies that apply in different situations.

## **What are the notification responsibilities at the receiving establishment?**

When an establishment receives adulterated or misbranded product and the product has been shipped in commerce, the receiving establishment must notify FSIS in accordance with [9 CFR 418.2](#). The receiving establishment may notify the District Office directly using the contact information provided on the [FSIS Contact Us](#) page or notify IPP. If the receiving establishment elects to notify IPP instead of the District Office, then IPP will complete FSIS Form 8140-1 to notify IPP at the shipping/producing establishment and the applicable District Offices. Notification should only be done using official FSIS email addresses and phone numbers for FSIS offices and FSIS issued electronic devices.

**NOTE:** The receiving establishment is required per [9 CFR 418.2](#) to either notify the District Office directly or IPP, but not both.

Even though FSIS will provide a copy of FSIS Form 8140-1 to the producing establishment, FSIS recommends that the receiving establishment notify the producing establishment to expedite the producing establishment's investigation.

## **What are the notification responsibilities at the producing establishment?**

When the producing establishment is notified directly by the receiving establishment that it produced adulterated or misbranded product and the producing establishment has not been notified by the local IPP that FSIS Form 8140-1 was received from the District Office, or when the producing establishment is notified of adulterated or misbranded product by a customer, the producing establishment must notify its District Office within 24 hours of learning that adulterated or misbranded product has entered commerce. When the producing establishment receives a customer complaint from a location other than an official establishment (e.g., state inspected, retail, restaurant, household consumer) that indicates adulterated or misbranded product has entered commerce, then the producing establishment is solely responsible for the notification of the District Office.

## **Customer Complaint Program Recommendations:**

FSIS recommends, but does not require, that an establishment develop a program to receive and process customer complaints. Customer complaints may originate from: another establishment, a household consumer, an FSIS inspector, the USDA Consumer Complaint Monitoring System (CCMS), or another regulatory agency. Regardless of the source, each customer complaint should be evaluated as a possible report of adulterated or misbranded product in commerce. When an establishment chooses to implement a customer complaint program, it should develop and maintain a program that addresses the receipt of complaints, investigation of complaints, implementation of corrective actions, and notification of FSIS that adulterated or misbranded product has entered commerce.

A customer complaint program may be used to meet existing regulatory requirements. For example, an establishment could include its customer complaint program as the initial steps in the establishment's recall procedures required by [9 CFR 418.3](#). When the evaluation, investigation, and corrective actions for FSIS regulated products are fully documented and available to FSIS for review upon request under a customer complaint program, the records of the program can be used to fulfil regulatory requirements in 9 CFR [418.4](#), [416.16](#), and [417.5](#).

## ➤ **Overview of the Program**

FSIS is making the following recommendations to assist establishments in the development of a customer complaint program. These recommendations do not constitute regulatory requirements. However, FSIS believes that a well-developed and implemented customer complaint program provides many benefits including: assisting establishments to comply with other regulatory requirements, reducing the long-term financial costs of recalls, and protecting public health by identifying adulterated or misbranded product earlier in the development of a recall scenario.

A consumer complaint program should include the following components that will be discussed in more detail in subsequent sections of this guideline:

- Customer Complaint Reporting
- Substantiation of the Customer Complaint
- Establishment Response to a Customer Complaint
  - Establishment Response Plan and Investigation
  - FSIS Notification
  - Corrective Actions
- Documentation of the Customer Complaint

## ➤ **Customer Complaint Reporting**

Each establishment should develop appropriate mechanisms to receive and process customer complaints.

The establishment should provide household consumers with a method for reporting a complaint, for example a:

- Postal address;
- Toll-free number;
- Website address;
- E-mail address.

The establishment should provide information to non-household consumers (e.g., other establishments, hotels, restaurants, or institutions) with a method for reporting a complaint, for example:

- Quality Assurance or management contact information;
- Instructions within the contract or bill of lading.

As technology and social networking develop, other methods for reporting complaints may be developed and incorporated into the customer complaint program. The establishment may provide contact information on product labels, shipping documents, or can post this information on the company's webpage.

Establishments that re-label or co-pack products should be aware that a customer might direct complaints to the company name on the label. As a result, co-packers should work with the company named on the label to develop a method for reporting and tracking complaints. When the establishment uses a 3<sup>rd</sup> party contractor to collect and process customer complaints or when complaints are directed to a corporate address, the establishment should consider how these complaints will be relayed to the producing establishment. The establishment customer complaint process may also include quality complaints or complaints regarding FDA-regulated products; however, a system should be in place to prioritize or triage those complaints that indicate adulterated or misbranded meat or poultry products have been produced at the establishment.

### ➤ **Substantiation of the Customer Complaint**

An establishment should develop criteria and a mechanism for determining the validity of any customer complaint. The establishment should start by verifying that the product is under the jurisdiction of FSIS. The next recommendation is to verify the establishment where the product was produced. Products are often similar and may be produced at multiple locations, so the establishment should verify that the product was produced at that location and, if not, notify the corporate office or customer if the product is not produced by that company. The establishment should also develop criteria to determine that no tampering of the product occurred after shipment from the producing establishment. The establishment should determine what evidence, if any, the customer has of the adulteration and misbranding. Evidence which can be used to substantiate a claim include:

- Photographs,
- Video, or
- A sample of the product label, product, and any other applicable material (e.g., foreign material).

The product label provides information to verify the source of the product including the lot number, establishment number, and product name. An image

### **Recommendation**

Establishments should develop criteria and a mechanism for determining if product was produced at that establishment and if a customer complaint is genuine, authentic, and no tampering of the product occurred after shipment from the producing establishment

or a sample of the product provides information to verify that the product matches the label and can show the condition of the product. An image or a sample of any physical adulteration such as foreign material provides information that can be used to start the investigation into the cause of the adulteration. The purchase location may also be helpful to identify distribution channels that may have contributed to the adulteration or misbranding.

**NOTE:** If the product does not match the label, this could be the basis of a misbranding claim and should be evaluated as evidence of misbranding.

Establishments should facilitate the substantiation of complaints as soon as possible when there is the potential that adulterated product is in the hands of household consumers. When the establishment determines that hands-on examination of the product, label, or any other material is important in determining if adulterated product has been produced, delays in the shipment of the identified foreign object, product, or label should be avoided. The recommended best practice is to perform an initial substantiation and investigation using immediately available photographic or video evidence and take appropriate action based on that evidence, then follow up with additional actions, as warranted, once the physical material, product, or label are made available for a hands-on examination.

The establishment should identify the specific establishment employee(s) (name or title) who will receive notification of the complaint and are responsible for the initial substantiation. Since complaints may occur on weekends, applicable contact information should be included in the program.

FSIS considers it a best practice for establishments to notify the local FSIS inspector that an investigation of a potential adulterated or misbranded product in commerce is underway. [9 CFR 418.2](#) requires the official establishment to notify the District Office within 24 hours of learning or determining that adulterated or misbranded product has entered commerce. However, best practice is to notify FSIS as soon as an establishment begins investigating a complaint, so FSIS can begin looking at distribution channels and verify that establishments have prevented further distribution of adulterated or misbranded products. Everyone benefits if a recall can be prevented by early notification and halting distribution.

When an establishment determines that a customer complaint claim is not valid or applicable to FSIS-regulated products, it is recommended that the establishment maintain documentation to support how that decision was made. Such documentation could be used to support why the establishment did not take any actions related to the product especially if new evidence, which does substantiate the initial claim, is identified in the future. It is not an FSIS regulatory requirement to maintain documentation related to products that are not regulated by or that do not impact FSIS-inspected products. However, if FSIS investigates at a future date, maintaining some documentation of the thought process that supports the product is not under the jurisdiction of FSIS and the shipment of the product is not a prohibited act under the FMIA or PPIA could be beneficial to the establishment. Some examples of why a claim may be found to be invalid include:

- Product not produced, distributed by, or owned at any point by that establishment/corporation.
- A valid complaint that was determined not to be an FSIS food safety concern, adulterated product, or misbranding. This could include quality complaints that are not related to adulteration or misbranding.
- Products that are not under FSIS jurisdiction when there are no implications for FSIS-inspected product.

The establishment must consider if any FSIS-regulated products are implicated by the complaint. The initial complaint may be related to a product under FDA jurisdiction; however when there are common ingredients or common production areas the implication to the FSIS-regulated products must be considered.

### ➤ **Establishment Response to a Customer Complaint**

When an establishment determines that a customer complaint represents adulterated or misbranded product that has entered commerce the establishment should respond by performing an investigation, notifying FSIS, and taking corrective actions. While it is not required that the establishment maintain a written plan for addressing customer complaints, it may be helpful for an establishment to do so to facilitate training and to document corrective actions.

#### *Establishment Response Plan and Investigation*

The establishment should quickly identify any affected product (e.g., lot, date, line, etc.) and identify distribution of the affected product. Drafting and maintaining a written response plan is the recommended best practice. The response plan should include an investigation of the production that incorporates a review of relevant records generated during the production of the affected product and may include performing a visual inspection of any questionable product or labels available, observing ongoing operations/production of like product, and talking to employees who may have information pertinent to the investigation. Affected product that has not been shipped should be held and inspected prior to shipping to determine if there are additional instances of adulteration or misbranding. The establishment should use additional information to evaluate the design and implementation of the HACCP system including laboratory sampling results, the intended use of the product, supporting documentation, and expert analyses. The response procedures may be incorporated into the establishment's written recall procedures ([9 CFR 418.3](#)) since some customer complaints may result in a recall.

The establishment should evaluate the HACCP system and reassess the HACCP plan to determine if the decisions in the hazard analysis or HACCP plan are still supportable. This is further discussed as part of the corrective actions below.

## *FSIS Notification*

Once the establishment has determined that adulterated or misbranded FSIS regulated product has entered commerce, [9 CFR 418.2](#) must be followed. Contact information for notification is provided on the [www.FSIS.USDA.gov](http://www.FSIS.USDA.gov) [contact us](#) webpage.

Remember, “in commerce” includes movement between official establishments when the product is not under direct control measures (e.g., preshipment review, written control programs, returned product to a corporate owned establishment, etc.). It is also good practice to notify the District Office of the nature of the adulteration or misbranding (e.g., foreign material contamination, ingredient not present on the label, etc.). The specific nature of each incident will determine the actions taken by FSIS in response to an official establishment producing adulterated or misbranded product that entered commerce.

The establishment should include in the response plan how it will gather the information required in [9 CFR 418.2](#) for notification of the District Office when product has been shipped in commerce.

The information required in [9 CFR 418.2](#) is:

- Product type
- Amount of implicated product
- Origin
- Destination

### **KEY QUESTION**

**Question:** Are meat and poultry establishments to report to FSIS every instance of product adulteration or misbranding of product that has entered commerce?

**Answer:** Yes, under [9 CFR 418.2](#), establishments are required to promptly (within 24 hours of learning or determining) report to the District Office all instances of adulterated or misbranded meat or poultry product received by or originating from the establishment *that has entered commerce*. Establishments that receive adulterated or misbranded product for further processing may notify Inspection Program Personnel (IPP) as a method to notify the District Office, and IPP will complete Form 8140-1, *Notice of Receipt of Adulterated or Misbranded Product*, in these instances.

When adulterated or misbranded product has entered commerce, the Agency may determine the need to convene the Health Hazard Evaluation Board (HHEB) as per [FSIS Directive 8091.1](#), *Procedures for the Food Safety and Inspection Service (FSIS) Health Hazard and Evaluation Board (HHEB)*. The HHEB may be convened if there are

circumstances that require further evaluation. Additionally, factors that are considered by the FSIS recall committee in evaluation of the public health significance of an undeclared ingredient in a meat or poultry product are described in Attachment 2 of [FSIS Directive 8080.1](#), *Recall of Meat and Poultry Products*. An establishment may wish to use [FSIS Directive 8080.1](#) as a reference when developing its customer complaint program and determining when a food safety hazard exists. Attachment 2 is specific to ingredients, but a similar thought process could be used to assess foreign materials, other contamination, and misbranding.

### *Corrective Actions*

When adulterated or misbranded product has been produced, the establishment must determine what part of the HACCP system failed. The incident may have occurred because of a deficit in the Sanitation SOPs, HACCP plan, or a prerequisite program. The system must be assessed to determine if safe and wholesome product can still be produced under the existing system or if modifications must be made. The specific requirements for corrective actions depend on which part of an establishment's HACCP system addresses foreign materials as described below.

#### ***What corrective actions are required for adulterated products?***

It is important to consider each customer complaint on a case-by-case basis. When a complaint is reported, the establishment must determine if a food safety hazard exists. An initial report of foreign material may not be a food safety hazard, however, consider if other implicated product may be adulterated with additional pieces of foreign material that *may* be a food safety hazard. If a food safety hazard has occurred, the establishment must address the regulatory requirements for HACCP corrective actions in [9 CFR 417.3](#) and documented as required in [9 CFR 417.5](#). This is further discussed below. If a food safety hazard does not exist, the product may still be adulterated and the establishment must react accordingly. If no food safety hazard exists, the regulatory requirements of

### **§417.3 Corrective actions**

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

- (1) The cause of the deviation is identified and eliminated;
- (2) The CCP will be under control after the corrective action is taken;
- (3) Measures to prevent recurrence are established; and
- (4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

(b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:

- (1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;
- (2) Perform a review to determine the acceptability of the affected product for distribution;
- (3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;
- (4) Perform or obtain reassessment by an individual trained in accordance with §417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

(c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with §417.4(a)(2)(iii) and the recordkeeping requirements of §417.5 of this part.

contaminated or adulterated products in [9 CFR 416.15](#) and [9 CFR 416.16](#) apply. This is further discussed in the Sanitation SOP section below.

***What corrective actions are required when the adulterant represents failure of a CCP or prerequisite program?***

If a food safety hazard posed by foreign material was previously identified as reasonably likely to occur (RLTO), a CCP was established to prevent the hazard from entering commerce, and the hazard then does occur in product in commerce, the establishment must implement corrective actions as described in [9 CFR 417.3\(a\)](#) (see regulation insert).

If the food safety hazard posed by the foreign material was identified through the hazard analysis as not reasonably likely to occur (NRLTO) due to a prerequisite program, but it does occur and foreign material entered commerce, then it would be an unforeseen hazard and the establishment must perform corrective actions as described in [9 CFR 417.3\(b\)](#). This corrective action requirement includes a reassessment to determine if the decision in the hazard analysis is still supportable or if changes need to be made. HACCP corrective actions must be documented as described in [9 CFR 417.5](#).

If product is adulterated and in commerce but the cause of the adulteration (e.g., foreign material) is determined not to be a food safety hazard, the establishment must still evaluate the efficacy of its HACCP system. Adulterated product that has been produced or shipped may indicate an inadequate HACCP system.

***What corrective actions are required when the adulterant represents a failure of the Sanitation SOPs?***

Sanitation SOPs must be designed to prevent the contamination or adulteration of product as outlined in [9 CFR 416.12\(a\)](#). When contaminated or adulterated food product is found in commerce, the Sanitation SOP may have failed to prevent direct contamination or adulteration of product and the establishment must perform corrective actions as described in [9 CFR 416.15](#) and document the corrective actions as described in [9 CFR 416.16](#).

***What corrective actions are required for misbranding?***

The establishment must not discount misbranding as a labeling issue alone, since misbranding may result in a food safety hazard. One example of misbranding that is also a food safety hazard is when allergens are present and undeclared on the label.

## Adulteration

Meat and poultry products that are contaminated with foreign materials are adulterated under the FMIA (21 U.S.C. 601(m)) and PPIA (21 U.S.C. 453(g)) regardless of the physical characteristics of the foreign material (e.g., shape, size, hardness, etc.).

When an establishment determines that misbranded product has entered commerce, it is to notify the District Office as required by [9 CFR 418.2](#). Misbranding events may require relabeling and the establishment should consult with the FSIS Office of Policy and Program Development (OPPD) Labeling and Program Delivery Staff (LPDS) to determine how to correct or replace the inaccurate labels. Questions may be submitted to LPDS through [askFSIS](#) by selecting Product “labeling” and the appropriate category for the question or by calling 1-800-233-3935 and selecting option 4.

### ***What other measures can an establishment implement?***

Establishments should be proactive in response to any adulteration or misbranding event and evaluate how the affected product was adulterated or misbranded, why it was shipped undetected, and assess the HACCP system for any other vulnerability.

For example, if a customer complaint is received regarding a piece of plastic in a food product and the plastic is determined to be from a single conveyor belt, the establishment should consider if this is really only an isolated incident. Best practice would be to re-inspect all of the belts and reevaluate the preventive maintenance program and controls that failed to detect the faulty belt resulting in adulterated product. Any corrective action should be meaningful and prevent additional adulterated or misbranded product from being produced at the establishment.

### **21 U.S.C. 610 and 458 Prohibited acts**

No person, firm, or corporation shall sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any such articles which are capable of use as human food and are adulterated or misbranded at the time of such sale, transportation, offer for sale or transportation or receipt for transportation.

### **➤ Documentation of the Customer Complaint**

Best practice is for an establishment to document all customer complaints (whether substantiated or not) and include the investigative steps that were performed and how the claim was or was not substantiated. For substantiated claims of adulterated or misbranded product in commerce, the records should include how FSIS was notified, what corrective actions were performed, if a HACCP reassessment was performed, and the result of the reassessment. The establishment should document how determinations were made and what evidence was used, even when a claim was not substantiated. The establishment should make records related to customer complaints available to FSIS for review upon request. This is a best practice recommendation so that establishments can support regulatory compliance based on their actions taken in the event a customer complaint is received. It is not a regulatory requirement. If an FSIS investigation occurs at a future date and the establishment has documentation to support that past complaints were not a prohibited act under the FMIA or PPIA, it can support the decisions in the establishment HACCP system.

Records of the investigations should include the following information:

- Dates of the complaint, any notification, corrective actions, recalls, etc.
- How the complaint was or was not substantiated
- Summary of the complaint including the complainant information
- Establishment number/manufacturing location on the product label
- Injury or illness reported
- Product details and trace back information (product code, lot numbers, date codes)
- Nature of foreign material (physical characteristics)
- Nature of misbranding, label information, label approval
- Notification of FSIS (who was notified, when, how)
- Potential causes or contributing factors
- Other implicated product (same line, date, lot, establishment)
- Corrective actions
- Preventive measures
- HACCP system reassessment

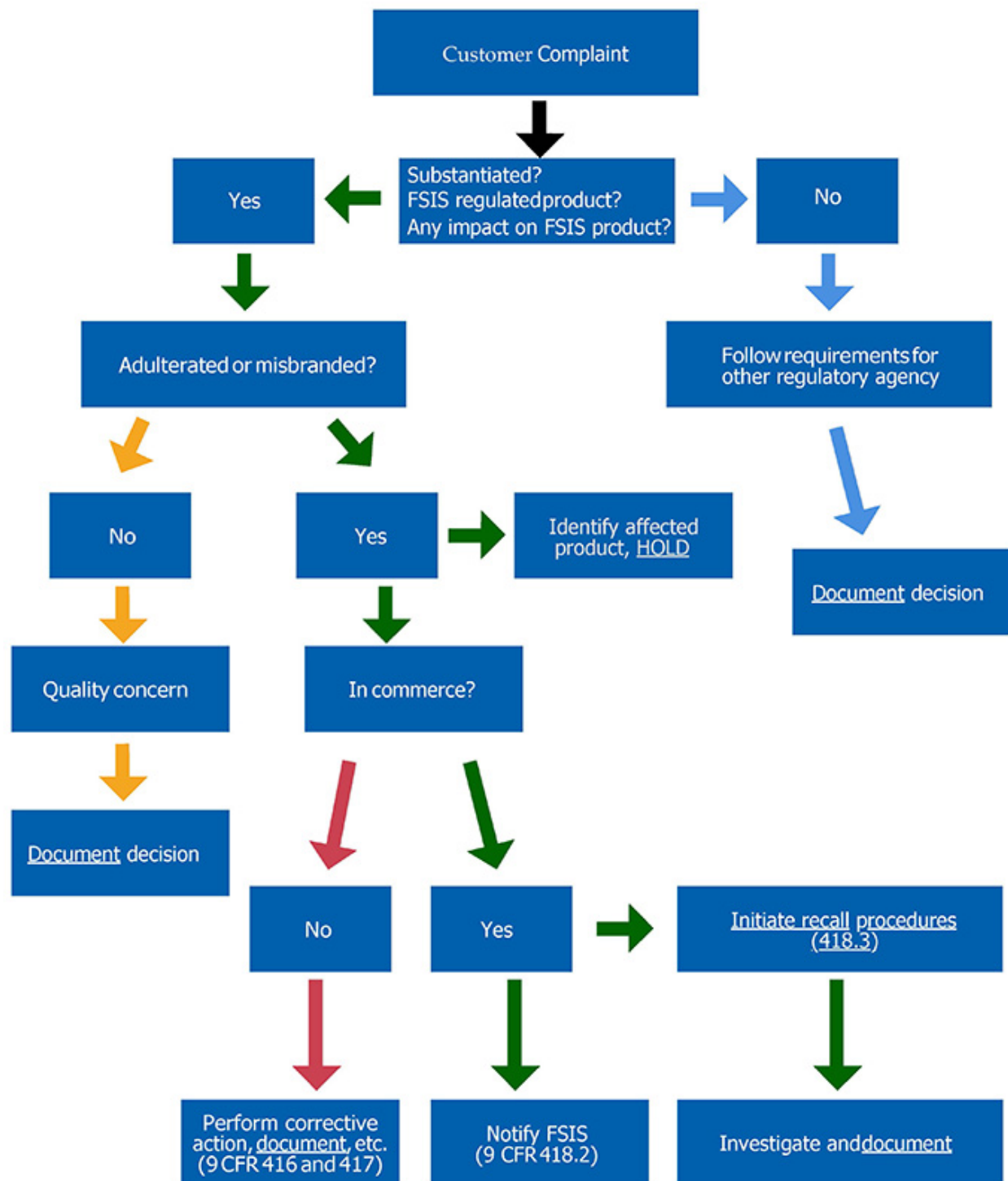
The investigation documentation should also include how the establishment identified all implicated product and support for the determination. The establishment may wish to consider factors such as the physical layout of the establishment, Sanitation SOPs, cleaning records, or testing results when developing the program.

## Suggested Tips:

Follow these tips when writing a customer complaint program:

- Provide customers with a method to notify you:
  - Consider the impact of co-packing or products produced in multiple establishments
  - Provide multiple modes of communication: email, telephone, mail, etc.
- Facilitate the substantiation of any complaint:
  - Pay to have a label or foreign material mailed to you
  - Ask questions to gather as much information as possible
  - Develop investigation SOPs
- Identify establishment and FSIS personnel who need to be notified and provide the contact information in the document so you don't have to look for it later:
  - District Office contact information is available on the Contact Us page of [www.FSIS.USDA.gov](http://www.FSIS.USDA.gov)
  - Frontline Supervisor (FLS) contact information may be obtained directly from the FLS
  - Inspection personnel office phone numbers are available to the individual establishment
- Evaluate the HACCP system;
- Document findings and make them available to FSIS upon request;
- Consider that the complaint may indicate a larger issue;
- Be proactive.

## Example Flow Diagram of a Customer Complaint



## References:

### REGULATIONS

United States Department of Agriculture, Food Safety and Inspection Service. 2012. Notification. [9 CFR Part 418.2](#).

United States Department of Agriculture, Food Safety and Inspection Service. 2012. Preparation and maintenance of written recall procedures. [9 CFR Part 418.3](#).

United States Department of Agriculture, Food Safety and Inspection Service. 1971. Reinspection, retention, and disposal of meat and poultry products at official establishments. [9 CFR Part 318.2](#).

United States Department of Agriculture, Food Safety and Inspection Service. 1970. Handling and disposal of condemned or other inedible products at official establishments. [9 CFR Part 314](#).

United States Department of Agriculture, Food Safety and Inspection Service. 1970. Transportation. [9 CFR Part 325](#).

United States Department of Agriculture, Food Safety and Inspection Service. 1972. Disposal of condemned poultry products. [9 CFR Part 381.95](#).

United States Department of Agriculture, Food Safety and Inspection Service. 1984. Poultry carcasses, etc., not intended for human food. [9 CFR Part 381.193](#).

United States Department of Agriculture, Food Safety and Inspection Service. 1970. Definitions. [9 CFR Part 301.2](#).

United States Department of Agriculture, Food Safety and Inspection Service. 2014. Definitions. [9 CFR Part 381.1](#).

United States Department of Agriculture, Food Safety and Inspection Service. 2014. Sanitation. [9 CFR Part 416](#).

United States Department of Agriculture, Food Safety and Inspection Service. 2014. Hazard Analysis and Critical Control Point (HACCP) Systems. [9 CFR Part 417](#).

### DIRECTIVES

[FSIS Directive 8080.1](#), *RECALL OF MEAT AND POULTRY PRODUCTS*

[FSIS Directive 8140.1](#), *NOTIFICATION OF ADULTERATED OR MISBRANDED PRODUCT*

[FSIS Directive 8091.1](#), *PROCEDURES FOR THE FOOD SAFETY AND INSPECTION SERVICE (FSIS) HEALTH HAZARD AND EVALUATION BOARD (HHEB)*

## **Helpful Websites (Control + click to be directed to website)**

Food Safety and Inspection Service (FSIS)-

FSIS homepage: <http://www.fsis.usda.gov/wps/portal/fsis/home>

Contact Us Webpage: <https://www.fsis.usda.gov/wps/portal/informational/contactus>

How to Develop a Meat and Poultry Product Recall Plan:

[https://www.fsis.usda.gov/shared/PDF/RecallPlanBooklet\\_0513.pdf](https://www.fsis.usda.gov/shared/PDF/RecallPlanBooklet_0513.pdf)

The Physical Hazards of Foreign Materials, Presentation at Public Meeting on Foreign Material Contamination, September 24, 2002, David P. Goldman, MD, FSIS

[https://www.fsis.usda.gov/wps/portal/fsis/newsroom/speeches-presentations/archive/presentations/ct\\_index999](https://www.fsis.usda.gov/wps/portal/fsis/newsroom/speeches-presentations/archive/presentations/ct_index999)

Food and Drug Administration (FDA)-

FDA Compliance Policy Guide, CPG Sec 555.425 Foods, Adulteration Involving Hard Sharp Foreign Objects

<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074554.htm>

Red Meat and Poultry Industry Guidance-

*Industry Best Practices for Customer Complaints of Foreign Material in Meat and Poultry Products*, August 2018.

[https://www.nationalchickencouncil.org/wp-content/uploads/2018/08/Foreign-Material-Best-Practices\\_Aug2018.pdf](https://www.nationalchickencouncil.org/wp-content/uploads/2018/08/Foreign-Material-Best-Practices_Aug2018.pdf)

**SMALL PLANT HELP DESK**  
A resource for small and very small plants  
Est. 12-17-2010

Knowledgeable, USDA-FSIS specialists from the Outreach and Partnership Division are available weekdays 8:00 AM to 4:00 PM EST to give you personal assistance on matters relating to the regulation of meat, poultry, and processed egg products. We can also be reached by email at [info@source@fsis.usda.gov](mailto:info@source@fsis.usda.gov).

**Call Toll-Free 1-877-374-7435**



**askFSIS**



***a policy-related question***

<http://askfsis.custhelp.com/>

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[www.fsis.usda.gov](http://www.fsis.usda.gov)  
**2019**